

R E M A R K S

By the present amendment, original claims 1-12 have been cancelled in favor of new claims 13-24. The new claims place the application in better form for examination. The amendments to the claims are not made for any reason related to patentability.

Additionally, the specification has been amended to add appropriate headings and an Abstract has been added.

An early action on the merits is respectfully requested.

Should the Examiner believe an additional amendment is needed to place the case in condition for allowance, he/she is invited to contact Applicants' attorney at the telephone number listed below.

No fee is believed to be due as a result of this response. Should the Commissioner determine that a fee is due, he is hereby authorized to charge said fee to Deposit Account No. 02-0184.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, DC 20231

on March 11, 2002  
(Date of Deposit)

Nicole Motzer

Name and Reg. No. of Attorney

Nicole Motzer

Signature

March 11, 2002

Date of Signature

Respectfully submitted,

GERARD VANACKER ET AL.

By

Barry L. Kelmachter  
Barry L. Kelmachter  
Attorney for Applicants

Area Code: 203  
Telephone: 777-6628 ext. 114  
Telefax : 865-0297

Date: March 11, 2002

## MARKED-UP COPY OF AMENDED PAGE

## FIXING ELEMENT AND ANCILLARY FOR STABILISING VERTEBRAE

BACKGROUND OF THE INVENTION

The present invention relates to the domain of spinal osteosynthesis intended for surgery of the vertebral column, to correct malformations of the degenerative or idiopathic, neuromuscular or tumoral, or of the traumatological type.

In prior art, it is known how to use an instrumentation comprising implants to be fixed on the bone, by screwing or by hooks and linkage elements enabling the surgeon to apply constraints for straightening or stabilising the vertebral column.

As an example, the European patent EP626828 describes such a system enabling osteosynthesis on the vertebral column, together with a linkage element between this system and the tools used for assembly and/or disassembly. This prior art document describes a device for osteosynthesis on the vertebral column, in particular for stabilising the vertebrae, comprising:

- at least one linkage element in the shape of a rod.
- at least two fixation elements each able to be anchored in a vertebra, these means having a head of the forked shape type whose two branches define a reception space closely U-shaped for the linkage element,
- a tightening screw able to be screwed in the reception space to fix the linkage element between the two branches of the fork-shaped screw head,
- the head whose bottom of the reception space is shaped in the form of a concave cup corresponding with a

## MARKED-UP COPY OF AMENDED PAGE

tilting bushing element fitted between the bottom of the reception space and the linkage element, the bushing

## MARKED-UP COPY OF AMENDED PAGE

screwing of each of these blocking screws is a fastidious and delicate operation.

SUMMARY OF THE INVENTION

The aim of the invention is to avoid these inconveniences by proposing a system and an implant making it possible to preserve the degree of correction decided by the surgeon during the operations of definitive fixation and tightening of blocking screws of the linkage element. The aim is also to allow rotation of the rod during its rotational manoeuvring, with minimum friction independent of the degree of tightening of the blocking screw.

Thus, the aim of the invention concerns in its most general form a device for osteosynthesis on the vertebral column, in particular for the stabilisation of vertebrae, comprising:

- at least one linkage element in the form of a rod, or plate,

- at least two means of fixation each able to be anchored into a vertebra, these means having a head in the shape of a fork whose two branches define a reception space closely in the form of a "U" for the linkage element,

- a blocking screw capable of being screwed in the reception space to fix the linkage element positioned between the two branches of the forked shape screw head, characterised in that the bottom of the head has the general shape of a horse saddle, in that the head has a guide means for an independent closure part capable of

## MARKED-UP COPY OF AMENDED PAGE

being fixed on the head after positioning the linkage element in the fork of the head, said closure part being in the general form of a "U" with branches coming into co-operation with the branches of the part in the shape

## MARKED-UP COPY OF AMENDED PAGE

instrumentation. This fixation element can be used with linkage elements other than rods, for example a linkage element with a trapezoid or variable cross-section, or laminae, in particular laminae having linkage zones of circular cross-section.

The invention also concerns an ancillary for the implementation of a system for osteosynthesis according to the invention characterised in that it presents two jaws which come to lodge in the cut-outs provided on the head of the implant, and a device exerting a force on the rod to ensure its lateral and/or vertical displacement, with the intention of enabling the positioning of the rod in the fork. This effort can be exerted on the rod through the intermediary of the closure part with which the ancillary co-operates during the phase of setting the rod in place in the fork of the implant. The co-operation can be carried out by temporary screwing of the ancillary in the threading of the closure part.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood by reading the following description of the attached drawings wherein:

- figure 1 shows a longitudinal cross-section of an embodiment of an osteosynthesis system according to the invention;
- figure 2 shows a diagram from the side of the system according to the invention, and
- figures 3 and 4 show a view of the implant according to two perpendicular faces.

## MARKED-UP COPY OF AMENDED PAGE

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

The osteosynthesis system according to the present invention comprises a linkage element (1), an implant (2) with a complementary closure part (3), and a blocking screw (13).

## CLEAN COPY OF AMENDED PAGE

## FIXING ELEMENT AND ANCILLARY FOR STABILISING VERTEBRAE

## BACKGROUND OF THE INVENTION

The present invention relates to the domain of spinal osteosynthesis intended for surgery of the vertebral column, to correct malformations of the degenerative or idiopathic, neuromuscular or tumoral, or of the traumatological type.

In prior art, it is known how to use an instrumentation comprising implants to be fixed on the bone, by screwing or by hooks and linkage elements enabling the surgeon to apply constraints for straightening or stabilising the vertebral column.

As an example, the European patent EP626828 describes such a system enabling osteosynthesis on the vertebral column, together with a linkage element between this system and the tools used for assembly and/or disassembly. This prior art document describes a device for osteosynthesis on the vertebral column, in particular for stabilising the vertebrae, comprising:

- at least one linkage element in the shape of a rod.
- at least two fixation elements each able to be anchored in a vertebra, these means having a head of the forked shape type whose two branches define a reception space closely U-shaped for the linkage element,
- a tightening screw able to be screwed in the reception space to fix the linkage element between the two branches of the fork-shaped screw head,
- the head whose bottom of the reception space is shaped in the form of a concave cup corresponding with a

CLEAN COPY OF AMENDED PAGE

*can't*  
*A,*  
tilting bushing element fitted between the bottom of the reception space and the linkage element, the bushing

---

CLEAN COPY OF AMENDED PAGE

---

screwing of each of these blocking screws is a fastidious and delicate operation.

## SUMMARY OF THE INVENTION

The aim of the invention is to avoid these inconveniences by proposing a system and an implant making it possible to preserve the degree of correction decided by the surgeon during the operations of definitive fixation and tightening of blocking screws of the linkage element. The aim is also to allow rotation of the rod during its rotational manoeuvring, with minimum friction independent of the degree of tightening of the blocking screw.

Thus, the aim of the invention concerns in its most general form a device for osteosynthesis on the vertebral column, in particular for the stabilisation of vertebrae, comprising:

- at least one linkage element in the form of a rod, or plate,
- at least two means of fixation each able to be anchored into a vertebra, these means having a head in the shape of a fork whose two branches define a reception space closely in the form of a "U" for the linkage element,
- a blocking screw capable of being screwed in the reception space to fix the linkage element positioned between the two branches of the forked shape screw head, characterised in that the bottom of the head has the general shape of a horse saddle, in that the head has a guide means for an independent closure part capable of

## CLEAN COPY OF AMENDED PAGE

*cont*  
*A2*

being fixed on the head after positioning the linkage element in the fork of the head, said closure part being in the general form of a "U" with branches coming into co-operation with the branches of the part in the shape

---

## CLEAN COPY OF AMENDED PAGE

---

instrumentation. This fixation element can be used with linkage elements other than rods, for example a linkage element with a trapezoid or variable cross-section, or laminae, in particular laminae having linkage zones of circular cross-section.

The invention also concerns an ancillary for the implementation of a system for osteosynthesis according to the invention characterised in that it presents two jaws which come to lodge in the cut-outs provided on the head of the implant, and a device exerting a force on the rod to ensure its lateral and/or vertical displacement, with the intention of enabling the positioning of the rod in the fork. This effort can be exerted on the rod through the intermediary of the closure part with which the ancillary co-operates during the phase of setting the rod in place in the fork of the implant. The co-operation can be carried out by temporary screwing of the ancillary in the threading of the closure part.

A3

## BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood by reading the following description of the attached drawings wherein:

- figure 1 shows a longitudinal cross-section of an embodiment of an osteosynthesis system according to the invention;
- figure 2 shows a diagram from the side of the system according to the invention, and
- figures 3 and 4 show a view of the implant according to two perpendicular faces.

## CLEAN COPY OF AMENDED PAGE

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

*cavt*  
*A3*

The osteosynthesis system according to the present invention comprises a linkage element (1), an implant (2) with a complementary closure part (3), and a blocking screw (13).

---

13. A system for osteosynthesis on the vertebral column for stabilization of vertebrae comprising:

at least one rod-shaped linkage element;

at least two fixation means to be anchored into a vertebra;

said fixation means having a head in the shape of a fork having two branches, said two branches defining a reception space closely in the form of a U for receiving the at least one rod-shaped linkage element;

*Ay*  
said head having a bottom in the shape of a horse saddle;

a blocking screw to be screwed in the reception space to fix the at least one linkage element between the two branches of the fork shaped screw head;

said head having a guide means for an independent closure part to be fixed on the head after positioning the at least one linkage element in the fork of the head;

said independent closure part being in the general shape of a U with branches cooperating with the branches of the fork shaped part of the head;

said closure part having a bottom which comprises a threading for cooperation with the blocking screw; and

said guide means provided on the head being formed by an arched shoulder on external lateral surfaces of the fork shaped part of the head.

*cat  
Q4*

14. A system for osteosynthesis according to claim 13, further comprising said closure part having a complementary shoulder for said guide means and said closure part being set by flexible spacing or shape memory of said fork branches and being anchored by contacting transverse surfaces of the shoulders during tightening of the blocking screw.

15. A system for osteosynthesis according to claim 14, wherein the shoulders provided on the lateral surfaces of the fork shaped head part are in the shape of an arc of a circle.

16. A system for osteosynthesis according to claim 14, wherein the shoulders have contact surfaces converging closely towards the threading for receiving the blocking screw.

17. A system for osteosynthesis according to claim 13, wherein said head is prolonged by a lower part in the shape of a hook for setting in place a pedicle and said hook comprises a flexible lamina for temporary maintenance.

18. A fixing element to be anchored onto a vertebra for osteosynthesis instrumentation, said fixing element comprising:

*cont*  
*Ax*  
a head in the shape of a fork having two branches, said two branches defining a reception space closely in the form of a U for receiving a linkage element;

said head having a bottom in the general shape of a horse saddle;

said head further having guide means for an independent closure part capable of being fixed on the head after said linkage element has been positioned in the fork of the head;

said closure part being in the general form of a U with branches co-operating with the fork branches;

said closure part having a bottom which comprises a threading for co-operation with a blocking screw; and

said guide means being formed by an arched shoulder on external lateral surfaces of the fork shaped part of the head.

19. A fixing element according to claim 18, wherein the closure part has a complementary shoulder and wherein said closure part is set by flexible spacing or shape memory of the fork branches and is anchored by contacting transverse surfaces of the shoulders during tightening of the blocking screw.

*cat  
A4*

20. A fixing element according to claim 19, wherein the shoulders provided on lateral surfaces of the fork shaped part of the head are in the form of an arc of a circle, allowing a degree of freedom for the linkage element relative to a fixation implant on a vertebral column.

21. A fixing element according to claim 19, wherein the shoulders have contact surfaces converging closely on the threading.

22. A fixing element according to claim 18, further comprising a lower part in the form of a hook for setting in place on the vertebra and said hook comprising a flexible lamina for temporary fixation maintenance.

23. An ancillary for use with a fixing element having an implant with a head, a rod linkage element, and a closure part having a threading for cooperating with a blocking screw, said head having a shape in the form of a fork with two branches and further having two cut-outs, said ancillary comprising:

*can't  
A.Y*  
two jaws which lodge in said cut-outs; and

a device exerting a force on the rod linkage element to ensure lateral and vertical displacement of the rod linkage element for enabling positioning of the rod linkage element in the fork.

24. An ancillary according to claim 23, further comprising said ancillary having a linkage zone with the closure part through the intermediary of a temporary screw co-operating with the threading.

---

#### ABSTRACT OF THE DISCLOSURE

The invention concerns an osteosynthesis system, comprising at least a linking element in the form of a rod, at least two fixing elements each capable of being anchored in a vertebra, and a locking screw. The invention is characterized in that the base of the head has a general horse-saddle shape, and the head has guide means for an independent closure component designed to be fixed on the head after the linking element has been positioned in the fork of the head, said closure component being generally U-shaped whereof the branches are urged to co-operate with the branches of the fork-shaped part of the head and whereof the base comprises an internal thread for co-operating with the locking screw and the guide means provided on the head is formed by an arc-shaped shoulder on the outer side surfaces of the fork-shaped part. The invention also concerns an ancillary and an element for fixing such a system.

AS